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#### NOTICE OF ALLOWANCE AND FEE(S) DUE

35969 7590 10/15/2009

Barbara A. Shimei Director, Patents & Licensing Bayer HealthCare LLC - Pharmaceuticals 555 White Plains Road, Third Floor Tarrytown, NY 10591 EXAMINER SAEED, KAMAL A

PAPER NUMBER

ART UNIT

DATE MAILED: 10/15/2009

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/500,096      | 01/11/2005  | Martin Hendrix       | LE A 35 821         | 7642             |

TITLE OF INVENTION: 2-HETEROARYLCARBOXYLIC ACID AMIDES

| APPLN, TYPE    | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE   |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | NO           | \$1510        | \$300               | \$0                  | \$1810           | 01/15/2010 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION NO THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

# Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

| INSTRUCTIONS: This<br>appropriate. All further<br>indicated unless correcte<br>maintenance fee notificat   | correspondence includir<br>d below or directed oth  | or trans<br>ig the F<br>ierwise                   | smitting the ISSU<br>atent, advance or<br>in Block 1, by (a  | TE FEE and PUBLIC<br>ders and notification<br>a) specifying a new of   | ofn  | naintenance fees w<br>pondence address;   | ill be<br>and/or                               | mailed to the current<br>(b) indicating a sepa  | rate "FEE .   | ence address as<br>ADDRESS" for  |
|--|---|---|--|--|--|---|--|---|---|--|
| CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)   |   |   |  | Note: A certificate of mailing can only be used for domestic mailings of the<br>Fee(s) Transmittal. This certificate cannot be used for any other accompanying<br>papers. Each additional paper, such as an assignment or formal drawing, must<br>have its own certificate of mailing or transmission. |  |   |  |   |   |  |
| 35969  | 7590 10/15  | /2009   |  |  |  | Cer   | tificate                                       | of Mailing or Trans   | mission   |  |
| Barbara A. Shii  |   |   |  |  | I he   | eby certify that th   | is Fee(  | Transmittal is being  | deposited   | with the United  |
| Director, Patents & Licensing<br>Bayer HealthCare LLC - Pharmaceuticals  |   |   |  |  | addr   | es Postal Service w<br>essed to the Mail<br>smitted to the USP  | Stop<br>FO (57                                 | s) Transmittal is being<br>ficient postage for firs<br>ISSUE FEE address<br>1) 273-2885, on the d                         | t class mail<br>above, or l<br>ate indicated                            | in an envelope<br>being facsimile<br>d below.  |
| Tarrytown, NY 1  | Road, Third Floor   |   |  |  |  |   |  |   |   | (Depositor's name)   |
| 11111101111,1111   | .0071   |   |  |  |  |   |  |   |   | (Signature)  |
|  |   |   |  |  | L  |   |  |   |   | (Date)   |
| APPLICATION NO.  | FILING DATE   |   |  | FIRST NAMED INVENTOR   |  |   | ATTORNEY DOCKET NO. CONFIRMATION NO.           |   |   |  |
| 10/500,096   | 01/11/2005  | •   |  | Martin Hendrix   |  |   |  | LE A 35 821   | 7   | 642  |
| TITLE OF INVENTION:  | 2-HETEROARYLCAP   | RBOXY   | LIC ACID AMII  | DES  |  |   |  |   |   |  |
|  |   |   |  |  |  |   |  |   |   |  |
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| APPLN. TYPE  | SMALL ENTITY  | ISS   | UE FEE DUE   | PUBLICATION FEE I  | OUE  | PREV. PAID ISSU   | FEE  | TOTAL FEE(S) DUE  | DA  | ATE DUE  |
| nonprovisional   | NO  |   | \$1510   | \$300  |  | \$0   |  | \$1810  | 01  | /15/2010   |
| EXAM   | INER  |   | ART UNIT   | CLASS-SUBCLASS   | S  |   |  |   |   |  |
| SAEED, K   | ED, KAMAL A   |   | 1626   | 514-412000   |  | JI.   |  |   |   |  |
| Change of corresponde<br>CFR 1.363).   | nce address or indicatio  | n of "Fe  | e Address" (37   | 2. For printing on   | the p  | atent front page, lis   | it .   |   |   |  |
|  |   |   |  | (1) the names of up to 3 registered patent attorneys or agents OR, alternatively,  |  |   |  |   |   |  |
|  | ondence address (or Cha<br>1/122) attached.   |   |  | (2) the name of a single firm (having as a member a 2  |  |   |  |   |   |  |
| ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Custome Number is required.                         |   |   |  | registered attorney or agent) and the names of up to<br>2 registered patent attorneys or agents. If no name is<br>isted, no name will be printed.  |  |   |  |   |   |  |
| 3. ASSIGNEE NAME AT  | ND RESIDENCE DATA   | A ТО В  | E PRINTED ON   | THE PATENT (print  | or typ   | e)  |  |   |   |  |
| PLEASE NOTE: Unle<br>recordation as set forth  | ess an assignee is ident<br>in 37 CFR 3.11. Comp  | ified be<br>detion o                              | low, no assignee<br>of this form is NO   | data will appear on t<br>I a substitute for filin  | he pa  | atent. If an assign<br>assignment.  | ee is io                                       | entified below, the de  | cument has  | s been filed for   |
| (A) NAME OF ASSIC  |   |   |  | (B) RESIDENCE: (0  |  |   |  |   |   |  |
|  |   |   |  |  |  |   |  |   |   |  |
| Please check the appropri  | ate assignee category or  | catego  | ies (will not be pr  | inted on the patent):  | ۵  | Individual 🗖 Co   | orporati                                       | on or other private gro   | up entity [   | Government   |
| 4a. The following fee(s) a   | are submitted:  |   | 41   | . Payment of Fee(s):   | (Plea  | se first reapply ar   | y prev   | iously paid issue fee   | shown abov  | ve)  |
| ☐ Issue Fee ☐ A check is en  |   |   |  |  |  |   |  |   |   |  |
|  |   |   |  |  | by credit card. Form PTO-2038 is attached.<br>ctor is hereby authorized to charge the required fee(s), any deficiency, or credit any |   |  |   |   |  |
| Advance Order - n  | of copies   |   |  | overpayment, to  | Depo   | sit Account Numbe   | er   | (enclose a  | extra copy  | of this form).   |
|  | SMALL ENTITY state  | is. See 3   | 7 CFR 1.27.  |  |  |   |  | TTY status. See 37 Cl   |   |  |
| NOTE: The Issue Fee and<br>interest as shown by the r  | I Publication Fee (if req<br>ecords of the United Sta   | uired) w<br>tes Pate                              | rill not be accepted<br>nt and Trademark   | from anyone other t<br>Office.   | han t  | he applicant; a regi  | stered.  | ttorney or agent; or th   | e assignee o  | or other party in  |
|  |   |   |  |  |  |   |  |   |   |  |
| Authorized Signature   |   |   |  |  |  | Date  |  |   |   |  |
| Typed or printed name  |   |   |  |  |  | Registration N  |  |   |   |  |
| This collection of informa<br>an application. Confident<br>submitting the completed<br>this form and/or suggestic<br>Box 1450, Alexandria, V<br>Alexandria, Virginia 223 | ation is required by 37 C<br>iality is governed by 35<br>application form to the<br>ons for reducing this but<br>irginia 22313-1450. DC<br>13-1450. | FR 1.3:<br>U.S.C.<br>USPTO<br>rden, sh<br>O NOT S | 11. The informatic<br>122 and 37 CFR<br>D. Time will vary<br>ould be sent to the<br>SEND FEES OR O | on is required to obtain<br>1.14. This collection<br>depending upon the<br>e Chief Information C<br>COMPLETED FORM   | n or r<br>is est<br>indiv<br>Office<br>IS TO   | etain a benefit by t<br>imated to take 12 i<br>idual case. Any co<br>r, U.S. Patent and<br>D'THIS ADDRESS | he pub<br>minuter<br>mment<br>Trader<br>i. SEN | ic which is to file (and<br>to complete, includin<br>s on the amount of tir<br>ark Office, U.S. Dep<br>D TO: Commissioner | by the USI<br>g gathering<br>ne you requ<br>artment of C<br>or Patents, | PTO to process),<br>preparing, and<br>fire to complete<br>commerce, P.O.<br>P.O. Box 1450, |

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Tarrytown, NY 10591

### UNITED STATES PATENT AND TRADEMARK OFFICE

#### UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

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| APPLICATION NO   | .   :      | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO. |  |  |
|--|------------|-------------|----------------------|---------------------------------|------------------|--|--|
| 10/500,096   | 01/11/2005 |             | Martin Hendrix       | LE A 35 821                     | 7642             |  |  |
| 35969  | 7590       | 10/15/2009  |                      | EXAM                            | IINER            |  |  |
| Barbara A. Shimei  |            |             |                      | SAEED, KAMAL A                  |                  |  |  |
| Director, Patents & Licensing  |            |             |                      | ART UNIT                        | PAPER NUMBER     |  |  |
| Bayer HealthCare LLC - Pharmaceuticals<br>555 White Plains Road, Third Floor |            |             |                      | 1626<br>DATE MAILED: 10/15/2009 |                  |  |  |

#### Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 490 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 490 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

## Notice of Allowability

| Application No. | Applicant(s)   |  |  |  |
|-----------------|----------------|--|--|--|
| 10/500,096      | HENDRIX ET AL. |  |  |  |
| Examiner        | Art Unit       |  |  |  |
| Kamal A Sagad   | 1626           |  |  |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable. PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- 1. This communication is responsive to communication filed on September 02, 2009.
- 2. The allowed claim(s) is/are 1-8, 11 and 16-62 now renumbered as 1-56.
- 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  $\square$  All b) ☐ Some\* c) ☐ None of the:
    - 1. T Certified copies of the priority documents have been received.
    - 2. Certified copies of the priority documents have been received in Application No.
    - 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) hereto or 2) to Paper No./Mail Date
  - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. 

DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

- 1. | Notice of References Cited (PTO-892)
- 2. Notice of Draftperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statements (PTO/SB/08). Paper No./Mail Date
- 4. T Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5. Notice of Informal Patent Application
- Interview Summary (PTO-413), Paper No./Mail Date
- 7. X Examiner's Amendment/Comment
- 8. X Examiner's Statement of Reasons for Allowance
- 9. ☐ Other

#### DETAILED ACTION

Claims 10, 13 and 14 have been canceled. Therefore, claims 1-9, 11, 12 and 15-62 are currently pending in this application. Claims 9, 12 and 15 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

## Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gabriel J. McCool on 9/23/2008.

The application has been amended as follows

The application has been amended as follows:

Delete claims 9, 12 and 15.

## Reasons for Allowance

Claims 1-8 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds of formula (I) and

Application/Control Number: 10/500,096

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pharmaceutically acceptable salts thereof, does not reasonably provide enablement for solvates thereof. Applicant's amendment filed on September 02, 2009 is sufficient to overcome the rejection. Nothing known in the art anticipates or renders the compounds and processes as described in this application obvious. Therefore, claims 1-8, 11 and 16-62 are allowable.

Any comments considered necessary by applicant must be submitted no later than the payment issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submittons should be clearly labeled "Comments on Statement for Reasons for Allowance."

## Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal A Saeed, Ph.D. phone number is (571) 272-0705. The examiner can normally be reached on M-T 7:00 AM- 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise requires a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is

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of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR only. For more information about the pair system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

/Kamal A Saeed/

Primary Examiner, Art Unit 1626